IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

KEVIN HART, Plaintiff, v. MEDTRONIC, INC., MEDTRONIC INTERNATIONAL, MEDTRONIC MINIMED, INC., JOHN DOES #1-10, ABC CORPS. #1-10, Defendants.	HONORABLE JEROME B. SIMANDLE Civil Action No. 1:16-cv-05403 (JBS-AMD) **OPINION**

APPEARANCES:

Joseph D. Cronin, Esq.
CRONIN LAW FIRM LLC
1500 John F. Kennedy Boulevard
Suite 1020
Philadelphia, PA 19102
Attorney for Plaintiff

Aaron Van Nostrand, Esq.
GREENBERG TRAURIG LLP
500 Campus Drive
Suite 400
P.O. Box 677
Florham Park, NJ 079321
Attorney for Defendants

SIMANDLE, District Judge:

I. INTRODUCTION

Plaintiff Kevin Hart (hereinafter, "Plaintiff") brought this suit against Defendants Medtronic, Inc., Medtronic

International[1], and Medtronic Minimed, Inc.[2], alleging that an insulin pump, designed, manufactured and sold by Defendants, caused serious injuries to Plaintiff. This matter comes before the Court upon the Defendant's motion to dismiss Plaintiff's Amended Complaint under Rule 12(b)(6), Fed. R. Civ. P.. [Docket Item 12.] The primary issue is whether Plaintiff's common law tort claims arising from use of a medical device that obtained premarket approval from the U.S. Food and Drug Administration ("FDA") are preempted by federal law, namely, 21 U.S.C. § 360k(a). For the following reasons, the motion to dismiss will be granted without prejudice to allow Plaintiff one final opportunity to propose a Second Amended Complaint setting forth a non-preempted claim, consistent with this Opinion.

II. BACKGROUND[3]

A. Factual Background

Kevin Hart, is an adult male residing in New Jersey. (Am. Comp. ¶ 1.) Plaintiff suffers from Type I diabetes. (Id. at ¶

[1] Defendants contend that there is no entity named "Medtronic International." (Def. Br. at 1, n. 1.)
[2] Plaintiff also lists an undetermined amount of fictitious persons and entities that are unknown at this time.
[3] For purposes of the pending motions, the Court accepts as true the version of events set forth in Plaintiff's Complaint, documents explicitly relied upon in the Complaint, and matters of public record. See Schmidt v. Skolas, 770 F.3d 241, 249 (3d Cir. 2014). The Court may consider these documents on a motion to dismiss without converting the motion to one for summary judgment. Id.

17.) To help control his diabetes, Plaintiff used the MiniMed 530G insulin pump (the "Pump") designed, sold, and manufactured by Medtronic, Inc. and Medtronic MiniMed, Inc. ("Defendants"). (Id. at ¶ 17.) On April 24, 2014, while Plaintiff was asleep, his Pump administered a potentially lethal dose of insulin. (Id. at ¶ 18.) When Plaintiff woke up and realized that he had been administered too much insulin, he went to the bathroom to attempt to remedy the situation. (Id. at ¶ 19.) Plaintiff ultimately lost consciousness, fell to the floor, and entered into a prolonged seizure. (Id. at ¶ 20.) As a result, Plaintiff sustained a series of injuries including head lacerations, severe bruising, severe muscle aches, hearing loss, tinnitus, chronic headaches, neck pain, nerve pain in the right arm, cracked teeth, diminished mental acuity and depression, as well as resulting "extreme economic hardship." (Id. at ¶¶ 21–22.) To treat the physical and mental injuries, Plaintiff alleges he sought the treatment of various specialists, underwent various diagnostic testing and physical therapy and received a root canal. (Id. at ¶ 22.)

B. **FDA Premarket Approval Process**

The medical device at issue is a Class III product that has gone through the rigorous "Premarket Approval Process" ("PMA)" before obtaining the FDA's approval for use, as now described. The FDA regulates medical devices pursuant to the Medical Device

Amendments (“MDA”) of 1976 to the Food, Drug and Cosmetic Act (“FDCA”). There are three classes of medical devices intended for human use -- Class I, Class II and Class III. 21 U.S.C. § 360c. The separate classes represent the different levels of oversight required by the FDA “depending on the risk [the device] presents.” Riegel v. Medtronic, Inc., 552 U.S. 312, 316 (2008). Class I devices –- elasticbandages, examination gloves, etc. -- are subject to the lowest level of oversight, for example, “labeling requirements.” Id.; see also 360c(a)(1)(A). Class II devices -- powered wheelchairs, surgical drapes, etc. -- are subject to more rigorous oversight, such as “performance standards and post market surveillance measures.” Riegel, 552 U.S. at 316; see also 360c(a)(1)(B). Class III devices -- replacement heart valves, pacemakers, etc.—receive the most arduous oversight.

Class III devices need to go through a Premarket Approval process that includes manufacturers submitting, among other things, “full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a full statement of the device's ‘components, ingredients, and properties and of the principle or principles of operation’; ‘a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and

installation of, such device'; samples or device components required by the FDA; and a specimen of the proposed labeling." Riegel, 552 at 318 (citing § 360e(c)(1)).

PMA does not end the oversight process for Class III devices. If the manufacturer wants to make any changes to the product it must apply for additional approval from the FDA, which is evaluated under similar criteria to the premarket approval. Id. at 319 (citing § 360e(d)(6)). Even if the manufacturer decides not to make any changes, it is still subject to reporting requirements such as needing to inform the FDA of any new clinical investigations concerning the device, or reporting incidents where the device may have caused death or serious injury or malfunctioned in a way that would likely contribute to death or serious injury if the malfunction occurred again. Id. (citing 21 C.F.R. §§ 814.84(b)(2); 803.50(a)).

C. MiniMed 530G Insulin Pump

The Pump is classified as a Class III product that has gone through the PMA approval process, and was approved on September 26, 2014. (Def. Br. at 5.) Since receiving the preapproval, Defendants have submitted and received approval for multiple changes to the original device. (Id.)

D. Procedural History

Plaintiff initially filed a Complaint before the Superior Court of New Jersey, Camden County, on April 18, 2016. (Docket Item 1 ¶ 1.) On September 6, 2016, Defendant timely removed the case to federal court alleging diversity jurisdiction pursuant to 28 U.S. C. § 1332. (Id. at ¶ 6). On November 10, 2016, Plaintiff filed an Amended Complaint, alleging six causes of action: (1) Strict Product Liability; (2) Negligent Design and Manufacture; (3) Post-Sale Negligence; (4) Failure to Test/Warn; (5) Breach of Warranty; and (6) Punitive Damages. [Docket Item 12.] Defendants filed a Motion to Dismiss, Plaintiff filed his Opposition, and Defendants filed their Reply. [Docket Items 18; 19; 20.] The motion is decided without oral argument pursuant to Rule 78, Fed. R. Civ. P..

III. STANDARD OF REVIEW

Pursuant to Rule 8(a)(2), Fed. R. Civ. P., a complaint need only contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Specific facts are not required, and "the statement need only 'give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.'" Erickson v. Pardus, 551 U.S. 89, 93 (2007) (citations omitted). While a complaint is not required to contain detailed factual allegations, the plaintiff must provide the "grounds" of her "entitle[ment] to relief," which requires more than mere

labels and conclusions. Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007).

A motion to dismiss under Rule 12(b)(6), Fed. R. Civ. P., may be granted only if, accepting all well-pleaded allegations in the complaint as true and viewing them in the light most favorable to the plaintiff, a court concludes that the plaintiff failed to set forth fair notice of what the claim is and the grounds upon which it rests. Id. A complaint will survive a motion to dismiss if it contains sufficient factual matter to "state a claim to relief that is plausible on its face." Ashcroft v. Iqbal, 556 U.S. 662, 663 (2009). Although a court must accept as true all factual allegations in a complaint, that tenet is "inapplicable to legal conclusions," and "[a] pleading that offers labels and conclusions or a formulaic recitation of the elements of a cause of action will not do." Id. at 678.

IV. DISCUSSION

A. Subsumption by the Products Liability Act

First, Plaintiff's claims for negligent design and manufacturing (Count Two), post-sale negligence (Count Three) and failure to test/warn (Count Four) are subsumed by the New Jersey Products Liability Act (PLA). See N.J.S.A. § 2A:58C-1(b)(3). Because they do not constitute viable separate claims under New Jersey law, they must be dismissed as a matter of law.

The PLA "established the sole method to prosecute a product liability action" such that "only a single product liability action remains." Tirrell v. Navistar Int'l, Inc., 248 N.J. Super. 390, 398-99 (App. Div. 1991). "The language chosen by the Legislature in enacting the PLA is both expansive and inclusive, encompassing virtually all possible causes of action relating to harms caused by consumer and other products." In re Lead Paint Litig., 191 N.J. 405, 436-47, 924 A.2d 484 (2007). It "effectively creates an exclusive statutory cause of action for claims falling within its purview." Repola v. Morbark Indus., Inc., 934 F.2d 483, 492 (3d Cir. 1991). It subsumes any cause of action "for harm caused by a product, irrespective of the theory underlying the claim, except actions for harm caused by breach of an express warranty." N.J.S.A. § 2A:58C-1(b)(3). In short, those former common-law causes of action (with the exception of breach of express warranty) have merged into a single cause of action under the PLA.

Because New Jersey law no longer recognizes negligence, failure to test/warn, and breach of implied warranty as viable separate claims for harm derived from a defective product, the Court will dismiss Count Two, Count Three and Count Four of Plaintiff’s Amended Complaint as a matter of law. What remains is a single strict product liability claim under the PLA (Count

One), breach of express warranty (Count Five) and a claim for punitive damages (Count Six). The Court will address such below.

B. FDCA § 360k(a) Preemption

Defendant argues that Plaintiff's claims, though pled as state-law claims, are preempted by § 360k(a) of the FDCA. The Medical Device Amendments of 1976, 21 U.S.C. § 360c et seq. (the "MDA"), expressly preempts certain state law requirements, stating that:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement - -
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

In Riegel v. Medtronic, Inc., the Supreme Court provided a two-step analysis for determining whether a claim is expressly preempted pursuant to the MDA. 552 U.S. 312, 321-22 (2008). First, the Court must determine whether the FDA has established requirements applicable to the medical device at issue. As relevant here, the Supreme Court has concluded that all Class III devices are subject to requirements that satisfy this first step in the analysis. Id. at 322 ("Premarket approval . . .

imposes 'requirements' under the MDA . . . .”); see also Hughes v. Boston Sci. Corp., 631 F.3d 762, 768 (5th Cir. 2011) ("Riegel established that any Class III device receiving PMA approval from the FDA will satisfy this first prong of the test . . . ." (citing Riegel, 552 U.S. at 322)); Dunstan v. Bayer Essure, Inc., No. 16-1458, 2017 U.S. Dist. LEXIS 163865, at *40 (E.D. Pa. Oct. 3, 2017).

Thus, the Court’s express preemption inquiry will focus on the second step, which dictates that the Court determine whether Plaintiff’s remaining state common law claims relate to safety and effectiveness and impose requirements that are "different from, or in addition to" those imposed by federal law. Riegel, 552 U.S. at 321 (quoting 21 U.S.C. § 360k(a)(1)). Where the state requirements do relate to safety and effectiveness and are "different from, or in addition to" the requirements imposed by federal law, any claims for violation of those state requirements are expressly preempted. Id. at 330 (quoting and citing 21 U.S.C. § 360k(a)(1)).

“Since the U.S. Supreme Court's decision in Riegel addressing preemption of claims involving medical devices, courts across the country [including the Third Circuit] have applied 21 U.S.C.S. § 360k(a) broadly, preempting all manner of claims from strict products liability to negligence.” Millman v. Medtronic, Civil Action No. 14-cv-1465, 2015 U.S. Dist. LEXIS

21750, at *15 (D.N.J. Feb. 24, 2015)(citing In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig., 592 F. Supp. 2d 1147, 1152 (D. Minn. 2009), aff'd, 623 F.3d 1200 (8th Cir. 2010)); see also Williams v. Cyberonics, Inc., 388 F. App'x 169, 171 (3d Cir. 2010) ("Appellants' allegations of strict products liability based on manufacturing defect and breach of warranty are pre-empted by the MDA."); Desai v. Sorin CRM USA, Inc., No. 12-2995, 2013 U.S. Dist. LEXIS 5795, 2013 WL 163298, at *4-6 (D.N.J. Jan. 15, 2013)(finding that the plaintiffs' claims under the N.J. Products Liability Act were preempted); Hayes v. Howmedica Osteonics Corp., No. 08-6104, 2009 U.S. Dist. LEXIS 131984, 2009 WL 6841859, at *6 (D.N.J. Dec. 15, 2009)(finding that a failure to warn claim is preempted); Delaney v. Stryker Orthopaedics, No. 08-03210, 2009 U.S. Dist. LEXIS 16865, 2009 WL 564243, at *3 (D.N.J. Mar. 5, 2009) (holding that "the MDA preempts products liability claims, including" failure to warn, defective design, negligence and breach of implied warranty); Gross v. Stryker, 858 F. Supp. 2d 466, 490 (W.D. Pa. 2012)(stating that breach of implied warranty is a state claim "that imposes requirements that are different [from], or in addition to, specific federal requirements"); Bentzley v. Medtronic, Inc., 827 F. Supp. 2d 443, 453 (E.D. Pa. 2011)(deciding that design defect claims are preempted); Mayen v. Tigges, 36 Misc. 3d 1231[A], 959 N.Y.S.2d 90, 2012 NY Slip Op

51565[U], 2012 WL 3553378, at *1 (N.Y. Sup. Ct. Aug. 17, 2012)(holding that the plaintiff's state law claims for design and manufacturing defect, negligent design, failure to warn and breach of warranties were preempted by the FDA through the PMA process for Class III medical devices).

However, not all state claims are expressly preempted by the MDA. Riegel recognized that claims alleging that a manufacturer failed to adhere to the specifications imposed by a device's premarket approval are not preempted. Such claims are not preempted because they merely parallel federal requirements -- that is, they do not add to or differ from federal requirements, which is the cornerstone of Food, Drug, and Cosmetic Act (FDCA) medical device preemption. Riegel, 552 U.S. at 330(citing 21 U.S.C. § 360k(a)(1)).[4]

[4] Plaintiff's reliance upon Medtronic, Inc. v. Lohr, 518 U.S. 470, 502 (1996), for the proposition that "the Supreme Court held that a plaintiff's manufacturing and warning defects claims survived preemption because they were outside of the category of requirements under § 360(k) [sic]" is incorrect. Lohr involved a device approved through the FDA's § 510(k) process, in which the FDA's requirements were not specific to the device in question, Riegel, 552 U.S. at 322, which is inapplicable to the present pump device that has premarket approval with specific requirements. Id. at 322-23. Further, Plaintiff's reliance upon various prescription drug preemption cases -– namely, Wyeth v. Levin, 555 U.S. 555 (2009); McDarby v. Merck & Co., 949 A.2d 223 (N.J. App. Div. 2008); and Feldman v. Lederle Labs., 479 A.2d 374 (N.J. 1984) -- for the concept that the MDA does not preempt state-law remedies for failure to warn in this case is also misplaced. Each of these cases involves prescription drugs -- not medical appliances -- for which Congress has not enacted an

Nevertheless, the parallel claim exception to preemption requires more than just a change of terminology; a plaintiff "cannot simply incant the magic words '[Defendant] violated FDA regulations' in order to avoid preemption." Clements v. Sanofi-Aventis, U.S., Inc., 111 F. Supp. 3d 586, 598 (D.N.J. 2015) (citing In re Medtronic, 592 F. Supp. 2d 1147, 1158 (D. Minn. 2009)); see also Smith v. Depuy Orthopaedics, Inc., 2013 U.S. Dist. LEXIS 36776, 2013 WL 1108555, at *12 (D.N.J. Mar. 18, 2013)("[B]road references to federal regulations in pleadings are insufficient" to properly plead a parallel claim). Rather, the plaintiff must plead "facts showing action or inaction in [the] defendants' efforts to take part in the PMA process or implement its results." Smith, 2013 U.S. Dist. LEXIS 36776, 2013 WL 1108555, at *12 (citations omitted). In short, a "parallel claim," like any other, is subject to the pleading standards of Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 167 L. Ed. 2d 929 (2007).

1. Plaintiff's strict product liability claim is preempted by § 360k(a) of the FDCA

In Count One of his Amended Complaint, Plaintiff alleges that Defendants distributed a product, the pump that "was defective and negligently designed in that it was not reasonably

express preemption provision. See Wyeth, 555 U.S. at 574-75; Riegel, 552 U.S. at 327.

fit, suitable or safe for its intended and reasonably foreseeable purposes and uses." (Am. Compl. ¶ 32.) Plaintiff further alleges that the pump "failed to include safe and appropriate guards or other safeguards to protect Plaintiff and others from foreseeable risk of injury." (Id. at ¶ 33.) Additionally, Plaintiff alleges that the pump was defective "due to [Defendants'] failure to provide adequate warnings and/or instructions regarding the risks and dangers of the pump during intended and reasonably foreseeable uses, and by failing to adequately test the design from a safety standpoint." (Id. at ¶ 34.) Lastly, Plaintiff alleges that Defendants should be held strictly liable because the pump "was defective from a manufacturing standpoint in that it failed to conform to customer specifications and/or omitted expected safety features required by the stand of reasonable care." (Id. at ¶ 35.)

As noted above, since the insulin pump was cleared for sale through the PMA process, it is subject to federal requirements within the meaning of § 360k(a) of the MDA. See Riegel, 552 U.S. at 322. In alleging that the pump was defective for failing to contain sufficient safeguards, for failing to offer adequate warnings or instructions, or for failing to have undergone adequate testing of the design for safety, Plaintiff is bringing into question the testing, design, manufacturing and warning specifications that the FDA approved and requires for this Class

III medical device. To permit such state law causes of action would impose requirements different from, or in addition to, the FDA requirements for this very device. This is precisely what § 360k(a) preempts. Accordingly, Plaintiff's PLA strict product liability claims are expressly preempted by § 360k(a). Id.

As noted above, there is a narrow exception for a "parallel" claim, e.g., "a damages remedy for claims premised on a violation of FDA regulations." Riegel, 552 U.S. at 330. Thus, in order to hold Defendants liable, Plaintiffs must plead "facts showing action or inaction in [the] defendants' efforts to take part in the PMA process or implement its results." Smith, 2013 U.S. Dist. LEXIS 36776, 2013 WL 1108555, at *12 (citations omitted). The Court finds that Plaintiff has failed to do so. In fact, with regard to the PMA process, Plaintiff merely pleads that "[t]he mere fact [that] there was 'pre-market approval' does not mean that the specific device was not defective and this is not enough to overcome this claim." (Am. Compl. ¶ 29.) Nowhere in Plaintiff's Amended Complaint does Plaintiff set forth facts that can be construed as alleging that Defendants violated the FDA regulations. Moreover, the Court finds that Plaintiff's brief in opposition to Defendants' motion to dismiss is also void of such facts that could support a claim for violating the FDA regulations pertaining to the warnings, manufacture or sale of this device. Therefore, the Court finds

that Plaintiff's PLA strict product liability claim fails to attempt to set forth a "parallel claim" and it must be dismissed, as it is expressly preempted by § 360k(a) of the FDCA.[5]

2. Plaintiff's breach of express warranty claim is preempted by § 360k(a) of the FDCA

An express warranty claim is not preempted under the MDA if a Plaintiff can show that Defendants made "voluntary statements" that were "not approved by the FDA or mandated by the FDA about the use or effectiveness" of a medical device. See Cornett v. Johnson & Johnson, 211 N.J. 362, 392 (2012). At this juncture, Plaintiff need only meet the minimal pleading standards of Fed. R. Civ. P. 8 and Twombly. The Court finds that Plaintiff has failed to do so.

Under New Jersey law, a claim for breach of express warranty has three essential elements: "(1) that Defendant made an affirmation, promise or description about the product; (2)

[5] Similarly, the Court has searched Plaintiff's Opposition Brief for some elaboration of claims set forth in the Amended Complaint. Plaintiff's argument focuses upon failure to warn of the risks and danger of users "injecting themselves with an overdose of insulin." (Pl. Br. at 4.) Thus, Plaintiff argues that Defendants failed to warn him of dangers and risks associated with using the MiniMed 530G insulin pump. (Id. at 5.) Plaintiff does not allege that Defendant failed to provide the instructions and warnings approved and required by the FDA for this device. To allege that the FDA's instructions and warnings on this Class III medical device emerging from the PMA process were inadequate or failed to balance safety and efficacy is to allege a claim that is preempted by 21 U.S.C. § 360k(a).

that this affirmation, promise or description became part of the basis of the bargain for the product; and (3) that the product ultimately did not conform to the affirmation, promise or description." Snyder v. Farnam Companies, Inc., 792 F. Supp. 2d 712, 721 (D.N.J.2011) (citing N.J. Stat. Ann. § 12A:2-313).

In a rather boiler plate fashion, Plaintiff merely alleges that Defendants "expressly and impliedly represented to Plaintiff that [the pump] was safe and proper for its intended use and purpose, and guaranteed to the ultimate consumer or user that [the pump] was of merchantable quality." (Am. Compl. ¶ 53.) Most notably, Plaintiff's Amended Complaint is void of any factual allegation that Defendants made any identifiable voluntary statements that were unapproved by the FDA regarding the safety or use of the pump.[6] Thus, in the absence of claiming a breach of the representations required by the FDA for this device (a "parallel claim") or an assertion that Defendants made

[6] Likewise, Plaintiff's Opposition Brief does not argue that Defendants made promises to the user that were beyond those appearing in the FDA-approved instructions and warnings. Instead, Plaintiff asserts that those instructions and warnings contained in the "User Safety" sections of Defendants' MiniMed 530G System User Guide, attached to Pl. Br. at Ex. B, were themselves inadequate or incomplete, because there was "no warning that the pump could deliver a fatal dose of insulin." (Pl. Br. at 6.) Again, such a claim does not sound in express warranty because it is based on an omission but even if it did, this claim is preempted because it takes issue with the adequacy of the FDA-approved warning on this Class III medical device issued under the PMA process. Therefore, the "warranty" claim is preempted by § 360k(a).

voluntary promises not required by the FDA and breached them, imposing liability on Defendants would amount to the improper imposition of safety requirements "different from, or in addition to" the requirements imposed by federal law. Riegel, 552 U.S. at 330. For this reason, the Court finds that Plaintiff's expressed warranty claim must be dismissed, as it is preempted by § 360k(a)of the FDCA.

3. Plaintiff's punitive damages claim must be dismissed.

A request for punitive damages is "similar to a derivative claim," and thus a "separate but dependent claim for relief." In re Collins, 233 F.3d 809, 811 (3d Cir. 2000). Because all of Plaintiff's substantive claims are dismissed, his claim for punitive damages must be dismissed as well.

V. CONCLUSION

For the foregoing reasons, the Court will dismiss Plaintiff's claims without prejudice.[7] An appropriate Order shall issue on this date.

November 30, 2017
Date

s/ Jerome B. Simandle
JEROME B. SIMANDLE
U.S. District Judge

[7] Plaintiff has not sought leave to further amend the Amended Complaint. However, the Court does not rule out that Plaintiff may be able to cure these pleading deficiencies. Plaintiff, who claims significant and permanent injuries, will be given one final opportunity to state a claim that is not preempted by § 360k(a). If Plaintiff seeks to amend a non-preempted claim -- such as a parallel claim for breach of the FDA's requirements for this medical device, see, e.g., Riegel, 552 U.S. at 330 -- then Plaintiff shall file a motion to amend the Amended Complaint within twenty-one(21) days hereof. While the Court does not find that any further attempt to amend would be futile, counsel shall be mindful that any proposed Second Amended Complaint must be consistent with this Opinion and must conform to the requirements of Rule 11, Fed. R. Civ. P., containing a reasonable basis in fact and law formed after due investigation.